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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,295	08/23/2001	Stephen C. Knight	VEK-001.01	1054

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EXAMINER

PORTER, RACHEL L

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/938,295

Applicant(s)

KNIGHT, STEPHEN C.

Examiner

Rachel L. Porter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the application filed 8/23/01. Claims 1-18 are pending. The IDS's filed 6/11/02 and 2/10/03 have been entered and considered.

***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-13 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Exemplary claim 1 recites "a system for recruiting. . ." in the preamble.

However, the body of the claim recites only data, interfaces, and instructions. The examiner understands these "interfaces" and "instructions" to be software modules or programs for executing certain functions. However, it should be noted that data structures, such as computer software, which are not embodied on a computer readable media are considered descriptive material. They are therefore considered non-statutory because they are not capable of causing a functional change in a computer. As drafted, the claim fails to define any structural and functional interrelationships between the code (i.e. the engine) and other elements of a computer that permit the computer program's function to be realized. (See MPEP § 2106)

For a claimed invention to be statutory, the claimed invention must also produce a useful, concrete, and tangible result. Under this analysis, the present language of

exemplary claim 1 merely recites non-functional descriptive material, as no recitation of executable code being embodied on any medium or data structure is provided. Simply stated, the “instructions,” interfaces and data as recited in claim 1 would fail to produce a tangible result.

Dependent claims 2-12 do not provide any further limitations that would serve to produce a useful, tangible, and concrete result and which fail to define any structural and functional interrelationships between the code and other elements of a computer that permit the computer program’s function to be realized. Thus, dependent claims 2-12 are also deemed to be non-statutory.

A similar analysis may be also be applied to claims 13 and 18, which also fail to define any structural and functional interrelationships between the code (e.g. the engine or computer program product) and other elements of a computer that permit the computer program’s function to be realized, and are therefore non-statutory.

In light of the above, it is respectfully submitted that the claimed invention, does not have a tangible result, and thus fails to recite the practical application of an abstract idea to satisfy the requirements of 35 U.S.C. 101.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson (USPN 2002/0002474).

[claim 1] Michelson discloses a system for recruiting a patient into a clinical trial, comprising:

- a patient interface; (par. 80-81 ; Figure 1A)
- a set of patient-specific data, collected from the patient through the patient interface; (par. 82-83)
- a set of trial-specific criteria corresponding to the clinical trial; (par. 88, e.g. IRB , budget data)
- a content interface;(Figure 1; par. 83 –e.g. subject site)
- a set of disease-specific data, collected from a disease expert through the content interface; and (Figures 7A-C; par. 84)
- instructions for matching, including instructions for coupling the set of patient-specific data to the disease-specific data and producing a set of patient-disease characteristics, and (par. 105-106)
- instructions for coupling the set of patient-disease characteristics to the set of trial-specific criteria and determining whether a match exists between the patient and the clinical trial. (par. 162-170)

[claim 2] Michelson discloses system of claim 1, wherein the patient interface comprises an HTML-encoded web page. (par. 80, 89-91 –internet implementation, webpage, Figures 6A-N)

[claim 3] Michelson discloses the system of claim 1, further comprising a patient database, including the patient-specific data. (par. 80-83)

[claim 4] Michelson teaches the system of claim 1, further comprising a clinical trial database, including the set of trial specific criteria. (par. 88, par. 162-170)

[claim 5] Michelson teaches the system of claim 1, further comprising a disease database, including the set of disease-specific data. (Figures 7A-C; par. 84)

[claim 6] Michelson teaches a system, wherein the patient-specific data, the disease-specific data, the trial-specific criteria, the instructions for matching, and the instructions for coupling are stored in a server. (par. 80-83)

[claims 7-8] Michelson discloses the system of claim 1, wherein the patient interface and content interface are adapted for transmission over a network to a remote location. (par. 80-83; internet implementation ; webpages)

[claim 9] Michelson discloses the system of claim 1, wherein the patient interface includes a series of questions. ; (par. 80-81 ; Figures 1A; 15A-E)

[claim 10] Michelson discloses a system further comprising instructions for coupling at least a portion of the patient-specific data to the clinical trial. (Figure 15E; par. 166-167)

[claim 11] Michelson teaches the system of claim 1, further comprising instructions for coupling a set of trial contact information to the patient. (Figure 14; par. 167-168)

[claim 12] Michelson disclose a system wherein the patient-specific data comprises at least one of patient contact information, disease of concern, demographic data, concomitant diseases, medications. (Figures 15A-E)

[claim 13] Michelson discloses a system for recruiting a patient into a clinical trial, comprising:

- a patient database, residing on a server and including a set of patient-specific data; (par. 80-83)
- a criteria interface coupled to the server over a network; (par. 80, Figure 9)
- a set of clinical trial criteria corresponding to the clinical trial and collected through the criteria interface; and (par. 166-167)
- instructions for comparing the set of clinical trial criteria to the set of patient-specific data to determine whether a match exists between the patient and the clinical trial. (par. 166-170)

[claim 14] Michelson discloses a method for recruiting a patient into a clinical trial, comprising:

- serving a content interface by a server to a first remote location over a network;(Figure 1; par. 80-83 –e.g. subject site)
- receiving a set of disease-specific data from the content interface over the network, the set of disease-specific data collected from a disease expert through the content interface; (Figures 7A-C; par. 80,84)
- serving a patient interface by the server to a second remote location over the network; (par. 80-81 ; Figure 1A)
- receiving a set of patient-specific data from the patient interface over the network, the set of patient-specific data collected from the patient through the patient interface; a set of patient-specific data, collected from the patient through the patient interface; (par. 80,82-83, 89-91, Fig. 6A-N)
- filtering the set of patient-specific data in comparison to the set of disease-specific data to generate a set of patient-disease characteristics; (par. 105-106)
- comparing the set of patient-disease characteristics to a set of trial-specific criteria corresponding to the clinical trial; and (par. 166-167)
- determining whether a match exists between the patient and the clinical trial. (par. 166-170)

[claim 15] Michelson discloses a method for recruiting a patient into a clinical trial, comprising:

- compiling a patient database including a set of patient-specific data; (par. 82-83)
- storing the database on a server; (par. 80-83)

- serving a criteria interface from the server to a remote location over a network;  
(par. 80, Figure 9)
- receiving a set of clinical trial criteria corresponding to the clinical trial from the criteria interface; and (par. 166-167)
- comparing the set of clinical trial criteria to the set of patient-specific data to determine whether a match exists between the patient and the clinical trial. (par. 166-170)

[claim 16] The limitations of claim 16 are addressed by the rejection of claim 14, and incorporated herein.

[claim 17] Michelson discloses a method of recruiting a patient into a clinical trial, the method comprising:

- receiving patient-specific data from a remote network device at a server; (par. 80-83; par. 162-170)
- accessing criteria of more than one clinical trial at the server; (par. 166-170)
- and determining one or more clinical trials having criteria satisfied by the patient-specific data. (par. 170)

[claim 18] Michelson a server system for recruiting a patient into a clinical trial, the server system comprising:

- sets of criteria corresponding to a different clinical trial; (par. 166-170)

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- instructions for receiving patient specific data from a remote network device; (par. 80-83; 162-170) and
- instructions for determining one or more clinical trials having criteria satisfied by the patient specific data. (par. 166-170)

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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C. LUKE GILLIGAN  
PATENT EXAMINER